Patient information leaflets - the state of the art

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Why do patients need more information?

Lack of information has been identified as a major factor among 250 reasons why patients do not take their medicines as the prescriber intends. Many studies have shown that at least 50% of patients may be involved. Provision of appropriate information in a suitable form is therefore crucially important. It is true that doctors sometimes do not give the information the patient needs. But in one study of general practice it was found that the patients had forgotten half of what the doctor had said to them within five minutes of leaving the consulting room. Patients will also deny having been told anything at all. Yet if they do not know exactly what is expected of them, they cannot use their medication correctly. A survey of almost 9000 patients in 1986 revealed that 55% did not know exactly how, when, or with what to take their medication[1]. Nearly all wanted more information.

There is another thrust for provision of information, from the patient as a consumer and a partner in the process of health care. People felt they have a right to know in order to make informed decisions about products; by extension, prescription drugs are included. But 80% of the 9000 patients knew nothing about potential side effects and this is in line with earlier studies, some of which have revealed that health care professionals did not give appropriate warnings and advice[2].

The desire for more information, failure to provide information, lack of understanding and forgetting of information presented orally, all point to the provision of information in print.

What information do patients require?

Surveys of patients, physicians and pharmacists in the United States[3,4] have shown the various types of information which a patient should be given. It is interesting to note much less support from physicians for informing patients about risks of using too little or not using the medication at all; or about all possible risks of normal use from both physicians and pharmacists. It has, however, been found that the giving of information which might be thought likely to have adverse effects does not result in either reduced compliance, increased anxiety, or a greater tendency to experience side effects.

A list of behaviours which the patient will display in proper use of the medication provides a useful basis for determining the information needed. Using this approach[5], the first item of one such list reads:

1. to know how to take the drug
   - 1.1 to take a specific dose
     - 1.1.1 amount of drug per tablet or other dosage form
     - 1.1.2 average dose and dose range, adult
     - 1.1.3 average dose and dose range, child

Unfortunately, the first sentence of the model leaflet is: 'It is an anti-infective medicine which acts against a wide range of germs by disturbing important life processes within them.' The authors do, however, suggest that usefulness of style and format need to be validated.

Minimum information for sensible use of self-prescribed medicines was considered by an international ad hoc working group spanning 16 countries. Consensus was reached for six common medicines. The group did not concern itself with presentation but noted the need to express the information in language which is non-technical and easy to digest and use[6].

Most recently, the ABPI has specified[7] that additional information should be as 'brief and succinct' as the regulations will allow, and give:

- name of drug
- purpose (though not always specific indications) and the importance of taking the drug
- dosage instructions
- method and times of administration (with particular reference to meals, where appropriate)
- duration of therapy
- precautions
- interactions which are clinically significant or potentially dangerous
- side effects important to patients and what to do if they occur
- relevant formulation details (including potentially sensitizing agents)
- action to be taken in the case of missed doses or overdosage
- advice to inform the doctor if pregnant
- what to do to get further information
- how to recognize if a medicine is not working and what to do about it.

Leaflets are to state clearly that they are limited in scope and content and refer to other sources for further information. In addition, consideration should be given to the needs of the blind and those who do not understand English. A compendium of patient information should also be published for reference by professionals and the public. Clearly, a 'full disclosure' approach has been adopted. It will be interesting to see if the publication of leaflets is accompanied by the same professional pro and con arguments advanced in the United States some 12 years ago[8].

How should the information be presented?

How can we determine readability?

Readability of written materials has received considerable attention in both clinical and non-clinical contexts. There are more than 50 formulae intended to predict the level of reading ability needed to understand a particular piece of prose[9]. They are usually based on derivation of a regression equation which best predicts the school grade reading level of passages in a standardized test. The contributing variables are usually word length in syllables, sentence length in words, and a measure of the proportion of common words. One formula, frequently used, is the Flesch Reading Ease formula:

$$RE = 206.835 - 0.846W - 1.015S$$

where: W = average number of syllables per random sample of 100 words; S = average number of words in the sentences. Reference to a table gives a verbal

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description of the level of difficulty of the text, and the proportion of the US adult population likely to understand at this level. The Flesch formula has been used in the design of leaflets in this country and has been applied to existing literature from drug companies[10,11]. There are, however, limitations which sometimes seem to be overlooked. It is, for example, inappropriate to apply any of the formulae to other than well-formed prose sentences. Nor is a formula sensitive to word-order or grammatical complexity. Sentences with badly positioned clauses, dangling participles, or misused vocabulary will score just as well as sentences of equal length which are well-written. 'Jabberwocky' scores at a level which should make it understandable by 95% of the American adult population! However, a poor score does suggest that there is something amiss. What is clear is that much patient education material requires a level of reading ability above the 8th grade reading level which is not attained by 30% of the American adult population. A review of patient education materials from nine sources of drug information dealing with the 10 most commonly prescribed drugs showed that some needed a second year college level[12].

How can we improve the comprehensibility of text?

Guidelines for the preparation of instructional prose materials can be derived from a number of sources, and there are useful bibliographies[13,14]. One author[15] lists 106 points, but such lists should be taken only as ideas to consider and only some have a sound research basis, often in a laboratory setting. Nevertheless, the following have been found useful:

(1) A clear, concise title at the beginning orientates the reader and assists subsequent recall.
(2) Headings and sub-headings, ranged from the left, together with a systematic use of space convey more readily the structure of a complex text.
(3) 'Adjunct questions', placed before the relevant text, encourage people to examine what they are reading and to look for related facts.
(4) Active, rather than passive, sentences should be used if possible. Writers with a scientific background seem particularly attached to use of the passive voice!
(5) Old, known information should be put at the start of a sentence and new information at the end.
(6) The order of mention should correspond with temporal occurrence.
(7) The majority of sentences should be simple or compound, rather than complex (with clauses).
(8) The majority of sentences should be in the affirmative.
(9) Negative sentences should only be used when emphasizing that actions should be avoided.
(10) Short sentences are preferable, and should contain not more than two ideas. However, there should be a reasonable balance to avoid the 'bittiness' of much advertising copy.
(11) Put 'because' and 'if' statements at the beginning of the sentence.
(12) Avoid 'unless' and 'except' clauses.
(13) Avoid too many participle phrases.
(14) Instructions should be specific rather than general (as suggested for oral instructions).
(15) Abstract words are less helpful than concrete.
(16) Avoid jargon and use common words whenever possible.

Even educated laymen have shown problems in understanding some single-syllable medical terms, eg germ[16-18], and quite a large area of ambiguity is found in carrying out what may seem to the professional to be a quite simple instruction.

Typography

Well-written and readable information needs further support. When printed, the size of type must be clear and large enough and be adequately spaced to be read. The layout must also help by attracting the reader, drawing attention to the information, and maintaining attention. The physical factors likely to affect the impact of written information include the format of the text, the size of the typeface, use of capitals and italics, use of colour, space between lines, length of lines, justified or unjustified lines. The following guidelines emerge from the literature[19,20]:

(1) Lines should be 50-89 mm long (this will typically give two columns on A4 width)
(2) 2.5 mm separation between lines is adequate.
(3) Unjustified lines are easier to read.
(4) Univers (no serif) typeface reduces the rate of comprehension.
(5) Typeface should be at least 10-point (a 'point' is 0.138 inch or 3 points per mm).
(6) Indenting the first line of a paragraph increases reading speed.
(7) Titles entirely in capitals are picked out less easily than lower-case.
(8) Italics reduce the speed of comprehension.
(9) Headings should be made to stand out, either by using space or a different typeface.
(10) Roman numerals are read less quickly and accurately than arabic numerals.
(11) Numbers are better written as numbers
(12) Highlighting points by colour or typographical cues, eg by boxing, is not helpful. A survey of the effects of oral contraceptive information showed that 87% of users thought that the box containing warnings gave instructions on use, although 54% did not know that the danger of blood clots was mentioned.

Illustrations

Extensive investigations[21] into the effectiveness of various kinds of illustrations of the heart, ranging from simple black and white line drawings to coloured photographs, showed that simple, labelled line drawings resulted in most learning. In patient information, colour might in any case be inappropriate.

It is tempting to think that illustrations will always assist learning, but there is some contrary evidence that one picture is not always worth a thousand words.

Cartoons intended to make text more interesting and attractive did not assist gout-sufferers who learned more from an unillustrated text. The cartoons may well have been a distraction.

The possibility of using illustrations as an alternative to text on prescription labels to assist poor readers had disappointing results, and we know that, in general, symbols are often misunderstood or cannot be interpreted by those for whom they are intended in non-clinical settings. A substantial number of poor readers, many who are semi-literate, continue to present an unresolved problem.

It is clear that diagrams can be useful, particularly in showing more complex manoeuvres, eg inserting suppositories or instilling eye-drops.

What are the effects of written information?

The majority of patients receiving written information express favourable attitudes, in some cases over 90%, and even to their treatment as a whole. A somewhat smaller percentage report reading the information, but in most studies this is more than 75%.

Effects on knowledge, compliance and therapeutic outcome have been examined in more than 30 studies. It is clear that knowledge is increased considerably, compliance somewhat less, and therapeutic outcomes are smallest (in four out of seven studies).

Patient information leaflets are to become a normal feature of health care in this country. Their advantages and benefits are evident. But they require careful preparation and the support of oral information at the point of delivery.

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Patient information - the present and the future

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Within the Association of the British Pharmaceutical Industry (ABPI), and indeed within the pharmaceutical industry throughout Europe, a great deal is happening on the patient information front. Before elaborating on this, however, may I make a personal comment; having been in general practice for many years, and holding the strong belief that one of the most important parts of each consultation is to explain to the patient the purpose and effects of the treatment chosen, I particularly welcome the decision which has been taken by the pharmaceutical industry - certainly in the UK, but also throughout most of Europe - to produce patient information leaflets particularly those which are going to be provided in original packs, as package inserts.

When I was in practice, for many (though not all) of my patients, the consultation included, or most often concluded with, the issue of a prescription. I always intended to accompany this with verbal instructions on how the medicine was to be taken, including expected side effects, what I hoped the medicine would do to the illness, and how it would help symptoms. I tried to remember to tell them how often to take the medicine and how much, or how many tablets, and perhaps most important of all, for how long the treatment would be needed. But I often forgot that - even though I was trying to achieve the ideal of always telling patients the information they actually needed; with hindsight I am certain I never achieved this ideal most of the time.

However, I reassured myself that the local pharmacists would give patients at least the basic information about the amount of medicine to be taken, and how often, with additionally a word of caution about possible side effects. Proper labelling, and the use of appropriate cautionary labels, introduced as a mandatory requirement by the Royal Pharmaceutical

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